

Rejections under 35 U.S.C. § 103 (a)

The Examiner rejected claims 3, 4 and 15 under 35 U.S.C. § 103 (a) as obvious in light of the combination of Lane et al. (1995) and Finkelstein et al. (1998). The Lane reference describes that intermittent human PTH administration at doses of 40 µg/kg or 400 µg/kg increases trabecular bone volume in ovariectomized, osteopenic rats. Finkelstein et al. describe that administration of 40 µg of human parathyroid hormone fragment (1-34) by subcutaneous injection prevents bone loss in women with GnRH analog-induced estrogen deficiency. The claims as amended are limited to the use of parathyroid hormone to prevent bone loss or stimulate bone formation in a host that is currently being treated with one or more glucocorticoid compounds or experiencing adverse bone effects resulting from contact with one or more glucocorticoid compounds, which is not described or suggested by Lane et al. or Finkelstein et al. One of ordinary skill in the art would not find it obvious based on the teachings of Lane and/ or Finkelstein that administration of PTH to animals or humans that are also being treated with glucocorticoids would prevent bone loss or stimulate bone formation. Applicants have made the surprising discovery that PTH prevents glucocorticoid-induced apoptosis of osteoblastic and osteoclastic cells. Applicants discovered that prevention of osteoblast apoptosis (i.e. increasing the lifespan of osteoblasts) is the principal mechanism for the anabolic effects of PTH on bone, prior to this time, the mechanism of action of PTH was unknown.

The Examiner rejected claim 20 under 35 U.S.C. § 103 (a) as obvious in light of the combination of Leafer et al. (1995) and Finkelstein et al. (1998). Applicants have cancelled this claim rendering this rejection moot.



Conclusion

In light of the amendments and comments presented herein, Applicants request that the Examiner allow all pending claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Steph D. Adams".

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

3. (twice amended) [The method of claim 24 wherein said bone-containing host is selected from the group consisting of a bone-containing host] A method of increasing the lifespan of osteoblasts in a bone-containing host in need of preventing bone loss or stimulating bone formation, wherein the host is currently being treated with one or more glucocorticoid compounds or the host is experiencing adverse bone effects resulting from contact with one or more glucocorticoid compounds, comprising the step of:

administering therapeutically effective dosages at least 10 micrograms per kilogram body weight of isolated parathyroid fragment wherein said parathyroid fragment is parathyroid hormone (1-34), to said host.

4. (twice amended) The method of claim 3 [24], wherein said administration is systemic, oral, intravenous, nasal spray or inhalation.

15. (amended) The method of claim 3 [24], wherein said host is a human.